



January 20, 2009

United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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Ms. Mary C. Till
Legal Advisor
Commissioner for Patents
United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Ms. Till:

This is in regard to the application for patent term extension for U.S. Patent No. 5,510,106, filed by the Regents of the University of California, under 35 U.S.C. § 156. The veterinary biologic product claimed by the patent is Fel-O-Vax® LvK/FIV vaccine (Feline Immunodeficiency-Leukemia Virus Vaccine, Killed Virus), which was assigned VS Code No. 15D5.R0 by the Center for Veterinary Biologics (CVB).

In the September 17, 2007, issue of the Federal Register (72 Fed. Reg. 52847-52849, Docket No. APHIS-2007-0121), the CVB published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before March 17, 2008, 180 days after the publication of the determination, any interested person could file a petition with the CVB under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and the CVB has received no such petition. Therefore, the CVB considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely,

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics

cc: Kevin L. Bastian
Townsend & Townsend & Crew
Two Embarcadero Center, 8th Floor
San Francisco, CA 94111-3834



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